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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH,

CENTRAL DIVISION

NUTRACEUTICAL CORPORATION,)
et al.,)

Plaintiffs,)

v.)

ANDREW VON ESCHENBACH, M.D.,)
Acting Commissioner of the U.S. Food)
and Drug Administration, et al.,)

Defendants.)

**PLAINTIFFS'
MOTION FOR SUMMARY
JUDGMENT**

(Oral Argument Requested)

Case No. 2:04-CV-00409-PGC

Pursuant to Federal Rule of Civil Procedure 56, Plaintiffs Nutraceutical Corporation and Solaray, Inc. (collectively “Nutraceutical”) respectfully move the court for summary judgment in their favor on their third and fourth claims for relief in their Complaint. Because Nutraceutical is entitled to summary judgment on those claims, Nutraceutical also moves this Court for: (1) a declaration that the Final Rule is invalid in violation of 5 U.S.C. §§ 553 and 706; (2) a remand of the matter to FDA for further rulemaking consistent with the Court’s opinion; and (3) an injunction prohibiting the Defendants from enforcing the Final Rule pending completion of that rulemaking.

This motion for summary judgment is made on the grounds:

1. There are no disputed issues of material fact concerning the third and fourth claims for relief and, as a matter of law, the legal issues must be decided in Nutraceutical’s favor.
2. With regard to the third claim, Nutraceutical is entitled to summary judgment because, as a matter of law, defendants violated the Administrative Procedure Act (“APA”) by failing to follow the publication and comment requirements when they *sua sponte* in their 2004 Final Rule adopted a risk-benefit comparison standard for determining the existence of adulteration in dietary supplements.
3. With regard to the fourth claim, Nutraceutical is entitled to summary judgment because, as a matter of law, defendants violated the APA requirement that FDA not take action that is arbitrary and capricious when FDA 2004 Final Rule determined ephedrine alkaloids, down to a molecule, are adulterated in dietary supplements but simultaneously exempted from the adulteration ruling ephedrine alkaloids in foods (teas) and traditional Asian medicines sold without a prescription, regardless of quantity.

This motion is supported by the Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Summary Judgment filed simultaneously with this motion.

Dated this 20th day of December, 2006.

SOLARAY, INC. AND
NUTRACEUTICAL CORPORATION

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CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of December, 2006, I electronically filed a true and correct copy of the foregoing PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT with the Clerk of the Court using the CM/ECF system which sent notification of such filing to the following:

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